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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,199	09/24/2001	Mitsuaki Yamamoto	213966US0PCT	6427

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
04/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/926,199	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2008 and 27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-71,73,74 and 86-88* is/are pending in the application.

4a) Of the above claim(s) *64-70,73,74 and 86-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62,63 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2008 and the corrected Reply of 1/27/2009 have been entered.

2. Claims 62 and 88 were amended. Claims 62-71, 73-74, and 86-88 are pending in the application, with claims 64-70, 73-74, and 86-88 currently withdrawn. Claims 62-63 and 71 are subject to examination below in light of the elected species of **digitonin** as the type of compound.

Manner of Making Amendments under 37 CFR 1.121

3. In the interest of expediting prosecution, Applicant's submission of 1/27/09 has been entered. However, Applicant is reminded of the proper format for amendments to the claims. The amendments to claims 62 and 88 are non-compliant because the word "comprising" appears both in plain text and with strike-through marks in line 2 of the claims, suggesting that the prior version of the claim included this word twice; however, the previous version of the claims (see the amendment of 12/13/2007) only recited the term "comprising" once in line 2. In future amendments, claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. See CFR 1.121 and MPEP 714.

Objections/ Rejections Withdrawn

4. The objection to the specification has been withdrawn in response to Applicant's amendments thereto.

5. The rejections of claims 62 and 71 under § 102(b) as being anticipated by Jones et al. are withdrawn in response to Applicant's amendments to claim 62, such that the claims now require that the reagent include all of the recited ingredients as a mixture.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 62 is rejected under 35 U.S.C. 102(b) as being anticipated by Kerscher et al. (U.S. 4,851,335) in light of the evidence of Hirai et al. (U.S. 4,940,660, of record).

Kerscher et al. teaches a reagent for the specific determination of cholesterol in serum, which contains cholesterol esterase, cholesterol oxidase, a non-ionic detergent, and optionally also **poly**ethyl**ene** glycol (i.e., a "polyene"). See especially at column 3, line 53 to column 4, line 52; and claims 1 and 10 in particular. The non-ionic detergent may be Triton X-100 (column 10, lines 59-60). Hirai et al. provides evidence that Triton X-100 is the trade name for polyoxyethylene (10) octylphenyl ether as recited instantly (see column 6, lines 55-57).

Therefore, in light of the evidence of Hirai et al., the teachings of Kerscher et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 62-63 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerscher et al. in view of Hino et al. (U.S. 5,773,304) and Kishi et al. (JP 9-313178; see also the attached machine translation obtained retrieved on 4/12/09 from http://www4.ipdl.inpit.go.jp and the attached partial translation from the JPO as retrieved via the EAST database on 4/12/09) and in light of the evidence of Hirai et al.

Kerscher et al. is as discussed above, which teaches a reagent for the specific determination of cholesterol which comprises cholesterol oxidase and cholesterol esterase, a non-ionic detergent, and a polyene (polyethylene glycol) (see column 3, line 53 to column 4, line 52; and claims 1 and 10 in particular).

However, Kerscher et al. fail to specifically teach that the reagent may include the elected species of **digitonin**.

Hino et al. teach that when measuring cholesterol, the enzymes cholesterol esterase and cholesterol oxidase may be combined and used as enzyme reagents. Alternatively, cholesterol esterase and cholesterol dehydrogenase may be combined (column 3, lines 33-39).

Kishi et al. teach that although methods of using cholesterol dehydrogenase for the purpose of measuring cholesterol were known, this enzyme is unstable (see especially the attached machine translation at [0003]). To solve this problem, Kishi et al. teach stabilized compositions that include a glycoside such as digitonin in addition to cholesterol dehydrogenase, in order to improve the stability and activity of the enzyme. See the machine translation at [0001]-[0003], [0008]-[0012] and also the attached JPO translation at pages 1-2, "Solution". (see especially the attached machine translation at). Such stabilized enzyme compositions can be used for determining cholesterol in blood [ibid].

The Courts have ruled that art-recognized equivalence between embodiments provides a strong case of obviousness in substituting one material for another. See MPEP 2144.06:

In the instant case, the teachings of Hino et al. indicate that cholesterol esterase can be combined with either cholesterol oxidase or alternatively with cholesterol dehydrogenase in order to form an enzyme reagent capable of being used in cholesterol determination.

Because cholesterol oxidase and cholesterol dehydrogenase were therefore recognized in the prior art to be functional equivalents for the purpose of cholesterol determination, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute

cholesterol dehydrogenase for cholesterol dehydrogenase in the reagent composition for determination of cholesterol determination of Kersher et al.

In addition, when employing cholesterol dehydrogenase in place of cholesterol oxidase, it would have been further obvious to include a glycoside such as digitonin (as taught by Kishi et al.) because Kishi et al. taught that such an additive stabilizes cholesterol dehydrogenase. Therefore, one would be motivated to include digitonin as a known additive to cholesterol dehydrogenase-containing compositions so as to obviate known stability issues associated with this enzyme and to improve the activity of this enzyme in the composition.

Conclusion

11. Claims 62-63 and 71 are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached at (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/
Examiner, Art Unit 1641

/Christopher L. Chin/
Primary Examiner, Art Unit 1641